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10/539,100	08/10/2005	Laurence Paris	2005-222	9260
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/539 100 PARIS, LAURENCE Office Action Summary Examiner Art Unit Douglas McGinty 1796 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-36 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-36 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

PTOL-326 (Rev. 08-06)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 6-15-05.

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities:

Line 3 has the term "extemporaneously". The person producing the composition is probably not a "stand-up" comedian, so the term should be changed to -- instantly – or whatever is supported by the application as originally filed.

Line 5 refers to "the medium", but antecedent basis is lacking.

Line 7 has the term "decomposition" but the chemical structure remains the same. If supported, the term should be – disintegrated –.

Line 9 refers to "it", but antecedent basis is lacking.

Claims 7-9 are objected to because of the following informalities:

The terminology "alkaline or alkaline-earth" apparently should be – alkali or alkaline-earth --.

Claim 17 is objected to because of the following informality:

The potato, com, etc. starches have undergone physical transformations to become starches. The whole plant is not thrown into the claimed composition.

Claim 32 is objected to because of the following informality:

The fourth from the last line has "at at", which apparently should read -- to at --.

Appropriate correction is required. It is respectfully requested that the claims be reviewed closely for definiteness and support in the written description as originally filed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

 Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 refers to alcohol content but it is unclear whether the alcohol is the hydroalcohol of claim 23 or the C₁₋₄ alcohols of claim 24. It may have been intended for claim 25 to depend from claim 24. See the Spec., p. 14, last paragraph.

Double Patenting

Claims 1-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/511,260.¹

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 10/511,260 also involves a viscous aqueous or hydroalcoholic composition used for manufacturing capsules. Claims 13 and 22 in that application recite carrageenans.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection may be overcome with a proper Terminal Disclaimer.

Claim Rejections - 35 USC §§ 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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This application has been published as US 2005/0244489.

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Paris (US 6,331,205).²

The present claims and the teachings of the reference are as follows:

Present claims	Teachings of Paris (US 6,331,205)
Claim 1 (original). Viscous aqueous or hydroalcoholic liquid compositions, buffered or not, intended for the production of films for the manufacture of soft	Aqueous viscous composition is taught for the manufacture of soft capsules. Abstract.

 $^{^2}$ US 6,331,205 issued more than one year before PCT/FR03/03740 was filed. US 6,331,205 also is equivalent to WO99/07347, published 2-18-99.

Apparently the term – disintegration – should have been used instead of "decomposition".

capsules,	
wherein gelatinization thereof is obtained extemporaneously starting with thickening agents that exhibit the unique property of gelatinizing instantly upon contact with complexing solutions,	Gelatization occurs with the addition of thickening agents. Col. 1, line 50, through col. 2, line 10.
the proportion of which in the medium exceeds 2%,	The thickening agent is > 5% in the medium. Col. 1, lines 55-60.
the elasticity of the films being obtained by introducing or not introducing a plasticizing agent,	Elasticity is controlled with plasticizers. Col. 3, lines 5-15.
decomposition ³ thereof being controlled by incorporating or not incorporating a surfactant or a polysaccharide, and	Disintegration is controlled with surfactants or polysaccharides. Col. 3, lines 20-67.
preservation thereof being ensured or not ensured by the addition of preservatives,	Preservation is controlled with preservatives. Col. 4, lines 1-10.
thus allowing it to contain oily and/or aqueous solutions.	The soft capsules may contain oily and/or aqueous solutions. Col. 4, lines 25-50.
Claim 2 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
wherein the thickening agents are the gum arabics and their derivatives, the lambda carrageenans, the pullulan gums and their derivatives, the rhamsan gums and their derivatives, the wellan gums and their derivatives.	The thickening agents include lamba carrageenans. Col. 2, lines 25 and 26.
Claim 3 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
wherein the concentration of thickening agents is between 2% and 80% by weight, relative to the final weight of the preparation.	The thickening agent is > 5% in the medium. Col. 1, lines 55-60.
Claim 4 (original). The viscous aqueous or hydroalcoholic liquid compositions,	

g gents.	The prior art taught using an additional gelling, i.e., thickening agent. Col. 2, lines 40-50.
two or more thickening agents.	gelling, i.e., thickening agent. Col. 2, lines
Claim 5 (currently amended). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim [claims 1 and] 4,	
	The amount of thickening agent may be >5% to 80%. Col. 2, lines 45-55.
Claim 6 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
	The amount of alcohol may be between 0 and 60%. Col. 2, lines 48-51.
Claim 7 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
agent is obtained by the introduction of	Solubilization agents include alkali and alkaline earth ions in the amount of 1-50 vol%. Col. 2, line 66, through col. 3, line 9.
Claim 8 (currently amended). The viscous aqueous or hydroalcoholic liquid	
compositions, buffered or not, according to [claims 1 and 7] claim 1,	
alkaline-earth ions varies from 0 to 50% by a	Solubilization agents include alkali and alkaline earth ions in the amount of 1-50 vol%. Col. 3, lines 5-10.
Claim 9 (currently amended). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to	

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claim 1 [claims 1 and 8],	
wherein the alkaline or alkaline-earth ion is introduced in the form of a hydroxide or a salt of hydrochloric, sulfuric, nitric, phosphoric, or citric acid, and derivatives.	The alkaline or alkaline-earth ion is introduced in the form of a hydroxide or a salt of hydrochloric, sulfuric, nitric, phosphoric, or citric acid, and derivatives. Col. 3, lines 1-5.
Claim 10 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
wherein the pH of the aqueous phase of the buffer solution of the dissolution medium for the thickening agents varies from 2 to 12.	The pH can vary between 5 and 12. Col. 2, lines 55-60.
Claim 11 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
wherein the buffered aqueous phase comprises one of the pairs: hydrochloride acid/sodium chloride, hydrochloric acid/potassium phthalate, hydrochloric acid/glycine, citric acid/citrates, citric acid/sodium hydroxide, lactic acid/lactate, monosodium phosphate/disodium phosphate or monopotassium phosphate/dipotassium phosphate/dipotassium phosphate/carbonate, potassium diphthalate/hydrochloric acid.	Various buffering systems, including the citrate, phosphate, phthalate, and carbonate systems, are taught. Col. 2, lines 50-65.
Claim 12 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
wherein the plasticizing agent belongs to the class of the polyols, of the type: glycerol, sorbitol, maltodextrins, dextrose, mannitol, xylitol, lactitol, propylene glycol, polyoxyethylene glycol 400 to 6000, natural and semi-synthetic glycerides, and their derivatives.	Plasticizing agents such as glycerol, etc., are taught at col. 3, lines 9-15.
Claim 13 (original). The viscous aqueous or hydroalcoholic liquid compositions,	

	wherein the content of starch and	Amounts of 0-20 vol% are taught at col. 3,
	Claim 18 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 16,	
	wherein the disintegrating agents are soluble potato, corn, rice, manioc, wheat starches that have or have not undergone chemical or physical transformations.	Corn, rice, manioc, wheat starches are taught at col. 3, lines 60-67.
	Claim 17 (currently amended). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 16 [1621],	
	wherein the surfactant providing control of the decomposition of the film belongs to the ionic, nonionic, and amphoteric classes of surfactant, and is combined with starch- type disintegrating agents.	lonic, nonionic, and amphoteric surfactants are taught at col. 3, lines 25-60. Starchtype disintegrating agents can be added as well. Col. 3, lines 60-67.
	Claim 16 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
	wherein the surfactant content varies from 0 to 20%.	The amount of surfactant can be 0-20 vol%. Col. 3, lines 60-65.
	Claim 15 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
	wherein the surfactant providing control of the decomposition of the film belongs to the ionic, nonionic, and amphoteric classes of surfactant.	lonic, nonionic, and amphoteric surfactants are taught at col. 3, lines 25-60.
	Claim 14 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
	wherein the proportion of plasticizing agent varies from 0 to 50% by weight, relative to the total weight of the preparation.	The plasticizing agent may be present in the amount of 0-30 vol%. Col. 3, lines 15-20.
Γ	buffered or not, according to claim 1,	

derivatives is between 0 and 50% by	lines 65-67.
weight, relative to the total weight of the	
preparation.	
Claim 19 (original). The viscous aqueous	
or hydroalcoholic liquid compositions,	
buffered or not, according to claim 1,	
bulleted of flot, according to claim 1,	
wherein preservative and/or coloring	Preservatives and/or coloring adjuvants
adjuvants are introduced.	are taught. Col. 4, lines 1-3.
Claim 20 (currently amended)	are taught. Cor. 1, mice 1 c.
The viscous aqueous or hydroalcoholic	
liquid compositions, buffered or not,	
according to claim 19 [23],	
according to claim 19 [20],	
wherein the preservative content ranges	Preservatives may be present in the
from 0.01 to 10% by weight, relative to the	amount of 0-10 vol%. Col. 4, lines 1-5.
total weight of the preparation.	
Claim 21 (original). The viscous aqueous	
or hydroalcoholic liquid compositions,	
buffered or not, according to claim 19,	
bulleted of flot, according to claim 10,	
wherein the coloring agent content ranges	The coloring agent can be 0.01-5 vol%.
from 0.01 to 5% by weight, relative to the	Col. 4, lines 5-10.
total weight of the preparation.	·
Claim 22 (original). The viscous aqueous	
or hydroalcoholic liquid compositions,	
buffered or not, according to claim 1,	
wherein the concentration of solid matter is	Opaque agents can be 0-10 vol%. Col. 4,
between 10% and 80% by weight, relative	lines 5-10.
to the final weight of the composition.	
Claim 23 (original). The viscous aqueous	
or hydroalcoholic liquid compositions,	
buffered or not, according to claim 1,	
wherein extemporaneous gelatinization	Saline solutions, i.e., acid salts, and
thereof is induced by saline solutions of	hydroalcoholic solutions are taught at col.
mineral or organic acids, or by	2, line 66, through col. 3, line 10.
hydroalcoholic solutions, or by a	
combination of the two solutions.	
Claim 24 (currently amended).	
The viscous aqueous or hydroalcoholic	
liquid compositions, buffered or not,	
according to claim 23 [claims 1 and 23],	
according to ciain 20 [ciains 1 and 20],	1

wherein gelatinization thereof is brought about by hydroalcoholic solutions containing ethanol, methanol, propanol, isopropanol, or butanol Claim 25 (currently amended). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 23 [claims 1 and 23],	
The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 23 [claims 1 and 23],	
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wherein gelatinization thereof is obtained for an alcohol content between 10% and 90% by weight, relative to the final volume of the hydroalcoholic complexing solution.	
Claim 26 (currently amended). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 23 [claims 1 and 23],	
wherein gelatinization thereof is brought about by saline solutions of salts of mineral or organic acids, and by hydroxides, oxides, and carbonates of calcium, barium, titanium, zinc, aluminum, sulfur, and silicas.	
Claim 27 (currently amended). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 23 [claims 1 and 23],	
wherein gelatinization thereof is obtained for a concentration of salts, hydroxides, oxides or carbonates in neutral, acid, or alkaline solution ranging from 1% to saturation of the medium. The amount of salts, he carbonates may be 0-can range from 5 to 12 through col. 3, line 10.	50 vol% and the pH 2. Col. 2, line 55,
Claim 28 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
wherein gelatinization thereof is obtained by spraying of or immersion in the complexing solution, or a combination of the two.	

Claim 29 (original). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1,	
wherein their gelatinization time in contact with the complexing solutions is between 10 seconds and 10 minutes.	
Claim 30 (currently amended). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1 [any of claims 1 to 29],	
wherein the films obtained from said viscous aqueous or hydroalcoholic liquid compositions, buffered or not, are lubricated with conventional edible oils or with glycerol esters and polyoxyethylene glycol esters, triglycerides, propylene glycol esters, and their derivatives, or dilute solutions of these various products.	Lubricants are taught at col. 4, lines 35-26.
Claim 31 (currently amended). The viscous aqueous or hydroalcoholic liquid compositions, buffered or not, according to claim 1 [any of claims 1 to 30],	
wherein the liquids capable of being contained in the capsules are aqueous and/or oily solutions.	The soft capsules may contain oily and/or aqueous solutions. Col. 4, lines 25-50.
Claim 32 (currently amended). A method for manufacturing films from viscous aqueous or hydroalcoholic liquid compositions, buffered Or not, according to claim 1 [any of claims 1 to 31], wherein it comprises:	
- producing, at cold temperatures or at a temperature not exceeding 90°C, a pseudo-colloidal solution by dispersion under vacuum of a thickening agent, alone or in combination with other thickening agents, in an aqueous or hydroalcoholic solution, buffered or not, containing	Processing steps are taught at col. 5, lines 30-55.

Claim 36 (original). The manufacturing	
wherein it comprises subjecting the produced mass, prior to the gelatinization step, to a vacuum degassing step to eliminate air, which is capable of forming bubbles during production of the films.	A vacuum is applied. Col. 5, lines 35-40.
Claim 35 (original). The manufacturing method according to claim 32,	
wherein encapsulation of the active ingredients using said films is accomplished by hot welding of the two films under pressure, at a temperature between 50°C and 100°C.	Temperatures of 70-100°C are taught at col. 5, lines 50-55.
Claim 34 (original). The manufacturing method according to claim 32,	
wherein it comprises subjecting the gelatinized film to a drying operation in an air stream whose temperature is between -10°C and +70°C.	Drying occurs at -4°C. Col. 5, lines 45-50.
Claim 33 (original). The manufacturing method according to claim 32,	
- gelatinizing the film mass by applying the complexing solution by spraying and/or by immersion, either simultaneously on both surfaces of the film or alternately after detachment of the film from its support.	The solution is transferred to the machines for processing, i.e., immersion. Col. 5, lines 40-50.
- producing films for soft capsules at a temperature maintained at at least 50°C;	Temperatures of 70-100°C are taught at col. 5, lines 50-55.
- maintaining that solution at 25°C while it is stored;	
alkaline or alkaline-earth ions, a plasticizer, a surfactant, and/or a disintegrating agent;	

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method according to claim 32,

wherein the produced mass is transferred to the film formation systems either by simple gravity or under pressure using endless screws or a press. The viscous mass is still liquid, so it flows "by simple gravity". Col. 5, lines 40-50.

The present claims substantially overlap the teachings of Paris. Thus, the prior art range discloses the claimed range with "sufficient specificity". MPE 2131.03, II.

With respect to Claim 24, Paris does not teach the C₁₋₄ alcohols claimed.

Nevertheless, that claim is a "product-by-process" claim which is not limited to manipulations of the recited steps. MPEP 2113. It is noted that the reference solution is heated under a vacuum. Paris, col. 5, lines 35-40. The same step would have driven off the volatile C₁₋₄ alcohols. The burden fairly shifts to the applicant to show an unobvious difference. MPEP 2113.

With respect to Claim 29, Paris does not specify a gelatinization time of 10 seconds to 10 minutes. Nevertheless, the reference does teach processing until a viscous mass is formed. Paris, col. 5, lines 30-45. Gelatinization would inherently occur within that time period, at the time the viscous mass forms. MPEP 2112 et seq.

With respect to Claim 32, Paris teaches an initial step of mixing the components together before the heating step. Paris, col. 5, lines 30-40. The claim does not specify how long the mixture is "stored", so the time could be as little as a few minutes. The temperature of 25°C is ambient or close thereto, such that one of ordinary skill would immediate envisage that temperature. MPEP 2131.02.

For the above reasons, Paris is found to anticipate Claims 1-36.

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Even if Paris did not anticipate those claims, they still would have been obvious in view of the teachings of that reference. Paris also teaches a viscous aqueous liquid or hydroalcoholic solution for the production of soft capsules, as discussed above.

Overlapping ranges would have been obvious. MPEP 2144.05, I. Obviousness only requires a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988); MPEP 2143.02, I. Times and temperatures would have been result-effective variables which would have optimizable through routine experimentation. MPEP 2144.05, II.A.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Paris as applied to claims 1-36 above, and further in view of Scott (WO 01/07507).

With respect to Claim 2, Paris does not specifically teach the recited thickening agents other than the carrageenans.

Nevertheless, Scott teaches those other thickening agents. Scott, p. 9, line 21, through p. 10, line 23. The reference also teaches the use of viscous aqueous liquids for making soft capsules. Scott, Abstract.

In view of the record as a whole, therefore, it would have been obvious to substitute the carrageenan taught by Paris with the other thickening agents taught by Scott because both references teach viscous aqueous compositions for making soft capsules and Scott further teaches that other thickening agents would work as well.

"The combination of familiar [components] according to known methods is likely to be

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obvious when it does no more than yield predictable results." KSR Intern. Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 (2007).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Douglas McGinty whose telephone number is (571) 272-1029. The examiner can normally be reached on M. W. Th. F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Douglas McGinty/ Primary Examiner Art Unit 1796